REMARKS

Claims 1 and 3-10 were pending in this application. According to the July 2, 1999 Office Action, claims 1 and 3-10 were rejected. Applicants have amended claims 1 and 9. Thus, claims 1 and 3-10 are now under consideration.

Applicants maintain that the amendments raise no issue of new matter. Specifically, support for 24 MIU/ml of interferon-beta may be found in the specification on page 5, line 24.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1 and 3-10 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention.

In response, applicants have hereinabove amended claims 1 and 9 according to the Examiner's suggestions in order to overcome this rejection.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 3, 7, 9 and 10 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,643,566 (Hanisch). The Examiner also rejected claim 5 under 35 U.S.C. §103(a) as allegedly unpatentable over Hanisch as applied to claims 1, 3, 7, 9 and 10 above, further in view of U.S. Patent No. 4,647,454 (Cymbalista). The Examiner further rejected claim 6 under 35 U.S.C. §103(a) as allegedly unpatentable over Hanisch as applied to claims 1, 3, 7, 9 and 10 above, further in view of U.S. Patent No. 5,004,605 (Hershenson).

In response, applicants respectfully traverse the Examiner's rejections. The present invention relates to a liquid pharmaceutical formulation consisting of from 0.6 to 24 MIU/ml of interferon-beta, **mannitol**, a buffer at a pH between 3.0 and 4.0 and, optionally, albumin. In contrast, Hanisch relates to pharmaceutical compositions comprising interferon-beta, **dextrose** and human serum albumin which composition is then lyophilized.

Accordingly, the Hanisch compositions differ from the composition of the present invention in several aspects. First, the compositions of Hanisch contain dextrose while the presently claimed compositions contain mannitol. Second, the compositions of Hanisch as acknowledged by the Examiner contain higher concentrations of interferon-beta (50 MIU/ml) immediately prior to lyophilization which implies that these higher concentrations are necessary to achieve stability and to efficiency during lyophilization. Accordingly, there is nothing in Hanisch either alone or in combination with the other cited references (i.e., Cymbalista and Hershenson) that teaches or suggests the composition of the present invention which is a liquid pharmaceutical composition containing interferon-beta and mannitol.

Nonetheless, and in order to expedite the allowance of this application, applicants have hereinabove amended claim 1 to limit the range of the interferon-beta concentration to from about 0.6 to 24 MIU/ml since the Examiner stated his willingness to allow claims with low dosage formulations because Hanisch implicitly teaches away from such dosages.

In light of the foregoing amendments and remarks, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited. If there are any issues or amendments the Examiner wishes to discuss, the Examiner is encouraged to contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on December 17, 1999:

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December 17, 1999

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Respectfully submitted,

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